

Unclassified

ENV/JM/MONO(2000)3



Organisation de Coopération et de Développement Economiques  
Organisation for Economic Co-operation and Development

OLIS : 16-Mar-2000  
Dist. : 21-Mar-2000

Or. Eng.

PARIS

**ENVIRONMENT DIRECTORATE  
JOINT MEETING OF THE CHEMICALS COMMITTEE AND  
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

Cancels & replaces the same document:  
distributed 20-Mar-2000

**OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE  
AND COMPLIANCE MONITORING  
Number 12**

**Advisory Document of the Working Group on Good Laboratory Practice**

**Requesting and Carrying Out Inspections and Study Audits in Another Country**

88802

Document complet disponible sur OLIS dans son format d'origine  
Complete document available on OLIS in its original format

ENV/JM/MONO(2000)3  
Unclassified

Or. Eng.



OECD Environmental Health and Safety Publications

Series on Principles of Good Laboratory Practice  
and Compliance Monitoring

**No. 12**

**Advisory Document of the Working Group on GLP**  
**Requesting and Carrying Out Inspections and**  
**Study Audits in Another Country**

**Environment Directorate**

**ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT**

**Paris 2000**

**Also published in the Series on Principles of Good Laboratory Practice and Compliance Monitoring**

No. 1, *OECD Principles of Good Laboratory Practice (as revised in 1997)*

No. 2, *Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice (1995)*

No. 3, *Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (1995)*

No. 4, *Quality Assurance and GLP (1992)*

No. 5, *Compliance of Laboratory Suppliers with GLP Principles (1992)*

No. 6, *The Application of the GLP Principles to Field Studies (1992)*

No. 7, *The Application of the GLP Principles to Short-term Studies (1993)*

No. 8, *The Role and Responsibilities of the Study Director in GLP Studies (1993)*

No. 9, *Guidance for the Preparation of GLP Inspection Reports (1995)*

No. 10, *The Application of the Principles of GLP to Computerised Systems (1995)*

No. 11, *The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP (1998)*

© OECD 2000

*Applications for permission to reproduce or translate all or part of this material should be made to: Head of Publications Service, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France.*

## About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 29 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonize policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The work of the OECD related to chemical safety is carried out in the Environmental Health and Safety Division. The Environmental Health and Safety Division publishes free-of-charge documents in six different series: **Testing and Assessment; Principles on Good Laboratory Practice and Compliance Monitoring; Pesticides; Risk Management; Chemical Accidents** and **Harmonization of Regulatory Oversight in Biotechnology**. More information about the Environmental Health and Safety Programme and EHS publications is available on OECD's World Wide Web site (see next page).

*This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC).*

**The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.**

**This publication is available electronically, at no charge.**

**For the complete text of this and many other Environmental Health and Safety publications, consult the OECD's World Wide Web site ([www.oecd.org/ehs/](http://www.oecd.org/ehs/))**

**or contact:**

**OECD Environment Directorate,  
Environmental Health and Safety Division**

**2 rue André-Pascal  
75775 Paris Cedex 16  
France**

**Fax: (33-1) 45 24 16 75**

**E-mail: [ehscont@oecd.org](mailto:ehscont@oecd.org)**

## Forward

Environmental health and safety studies for the assessment of chemicals and chemical products are increasingly being carried out in multiple sites. This holds not only for field studies, but also for various phases of toxicology studies. The Revised Principles of Good Laboratory Practice\*, adopted by OECD in 1997, cover the various aspects of the organisation of such studies. Nevertheless, the Working Group on Good Laboratory Practice felt that further guidance was needed about requesting and carrying out inspections and study audits of multi-site studies when the study site(s) are located in another country than that of the main test facility, as accorded by the 1989 Council Decision-Recommendation on Compliance with Principles of GLP [C(89)87(Final), Part II, 2.iii].

The Working Group therefore established a Steering Group on Multi-site Studies under the leadership of Germany. The Group met in Berlin on 2<sup>nd</sup> and 3<sup>rd</sup> September 1999 and included participants from the following countries: Denmark, France, Germany, the Netherlands, Sweden, Switzerland, the United Kingdom and the United States. It was chaired by Hans-Wilhelm Hembeck (Germany). The document prepared by the Steering Group was examined by the Working Group at its 12<sup>th</sup> Meeting in January 2000, where it was amended and endorsed.

The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology at its 30<sup>th</sup> Meeting in turn endorsed the document and recommended that it be declassified under the authority of the Secretary-General. The Joint Meeting recommended that it be published as an Advisory Document of the Working Party on GLP in the OECD series on GLP and Compliance Monitoring.

---

\* See No. 1 of the Series on GLP and Compliance Monitoring, OECD, Paris, 1998

## **Advisory Document of the Working Group on GLP**

### **RECOMMENDATIONS FOR REQUESTING AND CARRYING OUT INSPECTIONS AND STUDY AUDITS IN ANOTHER COUNTRY**

#### **Introduction**

In the 1989 Council Decision-Recommendation on Compliance with the Principles of Good Laboratory Practice (C(89)87/Final), Member countries decided that, for purposes of the recognition of the assurance by another Member country that test data have been generated in accordance with GLP Principles countries "shall implement procedures whereby, where good reason exists, information concerning GLP compliance of a test facility (including information focusing on a particular study) within their jurisdiction can be sought by another Member country." It is understood that such procedures should only be applied in exceptional circumstances.

The Working Group on Good Laboratory Practices proposed clarification of this decision based on the Revised OECD Principles of GLP and recommended the procedures set out below. This clarification was considered necessary, since it was recognised that some test facilities have test sites located under the jurisdiction of another country. These facilities or sites may not necessarily be part of the GLP compliance monitoring programme of the country of location, although many Member countries consider this desirable and useful.

The Working Group agreed, that the use of the term "test facility" in the 1989 Council Act encompassed both "test facility" and "test site" as defined in the Revised OECD Principles of GLP. Therefore any Member country can request an inspection/study audit from both test facilities and test sites located in another country. This request could concern any organisation associated with regulated GLP studies, whether these be main test facilities or test sites (dependent or independent of the test facility) which carry out phases of a study such as chemical analysis, histopathology or field studies.

Requests can also be made to inspect associated organisations such as independent Quality Assurance or archiving facilities if national legislation allows. However, this information exchange could be of a more informal nature and such operations need not necessarily appear in the Annual Overviews of Inspected Facilities exchanged among Members of the Working Group on GLP. These Annual Overviews should, however, include test facilities and test sites which were inspected or in which study audits were carried out.

In order to "implement procedures" to allow for this information exchange to take place smoothly and efficiently among monitoring authorities, to avoid duplication and wasting of resources and to assure that there is adequate compliance monitoring, the Working Group agreed that a process needed to be established for requesting inspections or study audits in another country.

The Working Group agreed that if justifiable requests to confirm compliance with GLP are made, every effort should be made to accommodate requests for inspections or study audits of test facilities or sites in other countries. If the country where the facility or site is located cannot accommodate the request in the framework of its current GLP monitoring programme and/or schedule, an alternative could be to allow the



requesting country to undertake the inspection and/or audit itself (at its own expense as mutually agreed by both parties). Refusal to accommodate such requests may result in rejection of studies from the facility or site concerned. It was agreed that all Members of the Working Group on GLP should be informed of such refusals and that the circumstances should be discussed in the Working Group.

**Recommended Procedures to be followed in requesting and carrying out inspections  
and study audits in another country**

1. The request for an inspection and/or study audit in another country should be made in writing and justified. The two countries should work out the arrangements to accommodate the request and for provision appropriate materials in a timely manner.
2. The liaison and lines of communication should be between the two national GLP Monitoring Authorities concerned.
3. The inspection/study audit will normally be led by the monitoring authority where the facility and/or site is located. An inspector or inspectors from the requesting country can be present at the inspection/study audit. Receiving authorities may participate if appropriate. The requesting country shall cover any costs involved for its own personnel.
4. The inspection/study audit report should be submitted to the requesting country (in an appropriate language as agreed between the two countries), with the appropriate measures taken to cover concerns about protection of commercial and industrial secrecy as required by national legislation.
5. Any major findings during such inspections/study audits should be followed up by the appropriate monitoring authority(ies).
6. Financial arrangements for inspections and study audits undertaken in this context will be made by the country in which they take place. The requesting country cannot be charged for this work.
7. Inspections and study audits undertaken in this context should appear in the Annual Overview of the country that led the inspection/study audit.